

37. (New) Composition according to claim 1 wherein the second particulate material has a Mohs hardness value of less than 3.

### REMARKS

#### Status of the Claims

Upon entry of the foregoing amendments, claims 1-37 will be pending. Claims 1-14, 16-24, 26-27, and 32-33 have been amended. Claims 36 and 37 have been added. No new matter has been added. In the Office Action, claims 1-5, 24, and 33 were rejected, and claims 6-23, 25-32, and 34-35 were objected to.

In view of the foregoing amendments and the arguments that follow, Applicants respectfully request withdrawal of all rejections or objections upon reconsideration.

#### Amendments

Claims 3, 6-14, 16-18, 20-23, 26-27, and 32 have been amended to resolve improper multiple dependency.

Claims 1, 24, and 33 have been amended to recite that the second particulate material have a Mohs hardness value of less than 6.5. Support for this amendment can be found, *inter alia*, in the specification as originally filed, page 9, lines 9-15.

Claims 2, 4-6, and 8-11 have been amended to recite a single size, weight, or hardness range previously recited in said claims.

Claim 19 has been amended to add the language "the group consisting of".

Claims 36 and 37 have been added to recite that the second particulate material have a Mohs hardness value of less than 4 and 3, respectively. Support for these new claims can be found, *inter alia*, in the specification as originally filed, page 9, lines 13-15.

#### The Present Invention

The present invention relates to mixtures of particulate materials comprising optionally a medicament(s) and aerosol compositions comprising these particulate materials and propellants.

DOCKET NO. CARP-0085

**Objections Under 37 C.F.R. 1.75(c)**

Claims 6-23, 25-32, and 34-35 were objected to under 37 C.F.R. 1.75(c) as allegedly being in improper form due to improper multiple dependencies and, thus, were not treated on the merits. Claims 3, 6-14, 16-18, 20-23, 26-27, and 32 have been amended to resolve any existing objectionable multiple dependencies. Applicants respectfully request that claims 6-23, 25-32, and 34-35 be treated on the merits.

**Rejections Under 35 U.S.C. §102(b)**

Claims 1-5, 24, and 33 stand rejected as allegedly being anticipated by Glaxo Group Limited (WO 96/19968, "Glaxo"). Applicants respectfully traverse this rejection.

The standard of anticipation is one of strict identity, requiring disclosure in a single piece of prior art of each and every limitation of a claimed invention. See *Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1363 (Fed. Cir. 1998). Applicants respectfully request reconsideration of this rejection, as the amended claims recite at least one limitation which is not disclosed in the Glaxo reference.

The Office Action asserts that Glaxo "discloses a pharmaceutical aerosol formulation for the administration of medicaments by inhalation comprising, a particulate medicament, at least one sugar, and a fluorocarbon or hydrogen containing chlorofluorocarbon propellant." (Office Action at page 3.) Glaxo states that typical sugars to be used are "sucrose, lactose and dextrose, preferably lactose, and reducing sugars such as mannitol and sorbitol." (Glaxo at page 4, lines 22-24.)

Claims 1-5, 24, and 33, as amended, however, recite that the second particulate material has a Mohs hardness value of less than 6.5. (Support for this limitation may be found, *inter alia*, in the specification as originally filed, page 9, lines 9-15.) Examples of soft materials suitable for use as the second particulate material include leucine and spray-dried lactose, as discussed in the specification at page 13, lines 8-15.

Glaxo, however, does not discuss the import of the softness of the particulate sugars, much less Mohs hardness values. } Accordingly, the present claims are not

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anticipated by Glaxo for at least this reason, and Applicants respectfully request that the rejection under 35 U.S.C. §102(b) in view of WO 96/19968 be reconsidered and withdrawn.

**Conclusion**

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version With Markings To Show Changes Made."

Applicants believe that the foregoing constitutes a full and complete response to the Office Action of record. Accordingly, an early and favorable Action is respectfully requested. Applicants invite the Examiner to contact the undersigned at 215-568-8352 to discuss any issues unresolved by this response.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE****In the Claims:**

Claim 1 has been amended as follows:

1. (Amended) Aerosol composition comprising a propellant and contained therein a first particulate material comprising particles having a median aerodynamic diameter within the range 0.05  $\mu\text{m}$  to 11  $\mu\text{m}$  and a second particulate material comprising particles having a median volume diameter within the range 15 to 200  $\mu\text{m}$ , wherein the second particulate material has a Mohs hardness value of less than 6.5.

Claim 2 has been amended as follows:

2. (Amended) Composition according to claim 1 wherein the second particulate material has a median volume diameter within the range 20 to 125  $\mu\text{m}$ [, preferably within the range 25 to 125  $\mu\text{m}$ , more preferably within the range 38 to 125  $\mu\text{m}$ , even more preferably within the range 45 to 125  $\mu\text{m}$  and even more preferably within the range of 63 to 125  $\mu\text{m}$ ].

Claim 3 has been amended as follows:

3. (Amended) Composition according to [any one of the preceding claims] claim 1 wherein the weight ratio of first particulate material to second particulate material in the composition lies in the range 1:0.1 to 1:500.

Claim 4 has been amended as follows:

4. (Amended) Composition according to claim 3 wherein the weight ratio of first particulate material to second particulate material in the composition lies in the range 1:10 to 1:100[, preferably in the range 1:25 to 1:67].

Claim 5 has been amended as follows:

5. (Amended) Composition according to claim 1 wherein the first particulate material has a median aerodynamic diameter within the range 1 to 10  $\mu\text{m}$ [, preferably within the range 1 to 5  $\mu\text{m}$ ].

Claim 6 has been amended as follows:

6. (Amended) Composition according to [any one of the preceding claims] claim 1 wherein the second particulate material has a Mohs hardness value of less than [6.5, preferably less than] 5[, even more preferably less than 4 and even more preferably less than 3].

Claim 7 has been amended as follows:

7. (Amended) Composition according to [any one of the preceding claims] claim 1 wherein the second particulate material has a Carr Index value:

for particles more than 100 um in size of less than 14%[, preferably less than 12%, even more preferably less than 10%];

for particles [less than] 40 to 100 um in size of less than 28%[, preferably less than 26%, even more preferably less than 24%];

for particles [less than] 20 to 40 um in size of less than 35%[, preferably less than 33%, even more preferably less than 31%]; and

for particles less than 20 um [is] in size of less than 65%[, more preferably less than 63%, even more preferably less than 61%].

Claim 8 has been amended as follows:

8. (Amended) Composition according to [any one of the preceding claims] claim 1 wherein the solubility of the first particulate material in the propellant is less than 49.9 wt% with respect to the total weight of the substance present in the composition comprising the first particulate material [present, preferably less than 10 wt%, more preferably less than 1.0 wt%].

Claim 9 has been amended as follows:

9. (Amended) Composition according to [any one of the preceding claims] claim 1 wherein the solubility of the second particulate material in the propellant is less than 49.9 wt% with respect to the total weight of the substance present in the composition comprising the second particulate material[, preferably less than 10 wt%, more preferably less than 1.0 wt%].

Claim 10 has been amended as follows:

10. (Amended) Composition according to [any one of the preceding claims] claim 1 wherein the composition comprises at least 80 wt% and up to 99.999 wt% propellant[, more preferably at least 90 wt% and up to 99.9 wt%].

Claim 11 has been amended as follows:

11. (Amended) Composition according to [any one of the preceding claims] claim 10 wherein the composition comprises at least 0.001 wt% and up to 20 wt% of the total of the first and second particulate material present[, preferably at least 0.1 wt% and up to 10 wt% of the total of first and second particulate material present].

Claim 12 has been amended as follows:

12. (Amended) Composition according to [any one of the preceding claims] claim 1 further comprising a surfactant, flavouring material, buffer, preservative or any mixture thereof.

Claim 13 has been amended as follows:

13. (Amended) Composition according to [any one of the preceding claims] claim 1 wherein the propellant is selected from the group consisting of chlorofluorocarbons, hydrofluorocarbons, and mixtures thereof.

Claim 14 has been amended as follows:

14. (Amended) Composition according to [any one of the preceding claims] claim 13 wherein the propellant is selected from the group consisting of hydrofluorocarbons and mixtures thereof.

Claim 16 has been amended as follows:

16. (Amended) Composition according to [any one of the preceding claims] claim 1 wherein the second particulate material is selected from carbohydrates including sugars, mono-, di-, tri-, oligo-, and poly-saccharides, and any physiologically acceptable derivatives, salts, forms, and solvates thereof, and any mixtures thereof.

Claim 17 has been amended as follows:

17. (Amended) Composition according to [any one of the preceding claims] claim 1 wherein the [and] second particulate material is selected from amino acids, di-, tri-, oligo-, and poly-peptides, proteins and any physiologically acceptable derivatives, salts, forms and solvates thereof and mixtures thereof.

Claim 18 has been amended as follows:

18. (Amended) Composition according to [any one of the preceding claims] claim 1 wherein the first particulate material is a medicament.

Claim 19 has been amended as follows:

19. (Amended) Composition according to claim 18 wherein the medicament is selected from the group consisting of salbutamol, salbutamol sulphate, terbutaline, terbutaline sulphate, ipratropium bromide or any physiologically acceptable salts or solvates thereof; beclomethasone dipropionate, budesonide, triamcinolone acetonide or any physiologically acceptable solvates thereof; corticosteroid, bronchodilator; peptides, proteins, nucleic acids or derivatives thereof; insulin, calcitonin, growth hormone, lutensing hormone releasing hormone, leuprolide, and oxytocin or any physiologically acceptable salts or solvates thereof, and [or] any mixture thereof.

Claim 20 has been amended as follows:

20. (Amended) Composition according to claim 18 wherein the medicament is salmeterol xinafoate, or any mixture thereof with any [medicament according to claim 19] one of the group consisting of salbutamol, salbutamol sulphate, terbutaline, terbutaline sulphate, ipratropium bromide or any physiologically acceptable salts or solvates thereof; beclomethasone dipropionate, budesonide, triamcinolone acetonide or any physiologically acceptable solvates thereof; corticosteroid, bronchodilator; peptides, proteins, nucleic acids or derivatives thereof; insulin, calcitonin, growth hormone, lutensing hormone releasing hormone, leuprolide, and oxytocin or any physiologically acceptable salts or solvates thereof, and any mixture thereof.

Claim 21 has been amended as follows:

21. (Amended) Composition according to claim [18 or] 19 wherein the medicament is salbutamol sulphate.

Claim 22 has been amended as follows:

22. (Amended) Composition according to claim 18 wherein the medicament is fluticasone propionate, or any mixture thereof with any [medicament according to claim 19] one of the group consisting of salbutamol, salbutamol sulphate, terbutaline, terbutaline sulphate, ipratropium bromide or any physiologically acceptable salts or solvates thereof; beclomethasone dipropionate, budesonide, triamcinolone acetonide or any physiologically acceptable solvates thereof; corticosteroid, bronchodilator; peptides, proteins, nucleic acids or derivatives thereof; insulin, calcitonin, growth hormone, luteinizing hormone releasing hormone, leuprolide, and oxytocin or any physiologically acceptable salts or solvates thereof, and any mixture thereof.

Claim 23 has been amended as follows:

23. (Amended) Composition according to claim 18 [or 19] wherein the medicament is beclomethasone dipropionate or a physiologically acceptable solvate thereof, or any mixture thereof with any [medicament according to claim 19] one of the group consisting of salbutamol, salbutamol sulphate, terbutaline, terbutaline sulphate, ipratropium bromide or any physiologically acceptable salts or solvates thereof; beclomethasone dipropionate, budesonide, triamcinolone acetonide or any physiologically acceptable solvates thereof; corticosteroid, bronchodilator; peptides, proteins, nucleic acids or derivatives thereof; insulin, calcitonin, growth hormone, luteinizing hormone releasing hormone, leuprolide, and oxytocin or any physiologically acceptable salts or solvates thereof, and any mixture thereof.

Claim 24 has been amended as follows:

24. (Amended) Pharmaceutical composition comprising a propellant and contained therein a particulate medicament comprising particles having a median aerodynamic diameter within the range 0.05 to 11  $\mu\text{m}$  and a second particulate material comprising particles having a median volume diameter within the range 15 to 200  $\mu\text{m}$ , wherein the second particulate material has a Mohs hardness value of less than 6.5.

Claim 26 has been amended as follows:

26. (Amended) A container according to claim [18] 25 wherein the valve outlet is a metered dose valve.



Claim 27 has been amended as follows:

27. (Amended) An inhalation device incorporating a container according to claim 25 [or claim 26].

Claim 32 has been amended as follows:

32. (Amended) The method according to [any one of claims 29 to] claim 31 wherein the container includes an outlet valve[, preferably a metered dose valve].

Claim 33 has been amended as follows:

33. (Amended) A mixture of first particulate material having a median aerodynamic diameter within the range 0.05 to 11  $\mu\text{m}$  and a second particulate material having a median volume diameter within the range of 15 to 200  $\mu\text{m}$ , wherein the second particulate material has a Mohs hardness value of less than 6.5.

Claim 36 has been added as follows:

36. (New) Composition according to claim 1 wherein the second particulate material has a Mohs hardness value of less than 4.

Claim 37 has been added as follows:

37. (New) Composition according to claim 1 wherein the second particulate material has a Mohs hardness value of less than 3.